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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,310	12/17/2004	Hidehito Kotani	262507US0PCT	6711

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EXAMINER	
SHAW, AMANDA MARIE	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 09/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/517,310	KOTANI ET AL.	
	Examiner	Art Unit	
	Amanda M. Shaw	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-23 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-23 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-4, 8, and 20-21, drawn to methods for determining a polymorphism of the nucleotide sequence of the ABCG2 gene.

Group II, claim(s) 1, 5-8, and 20-21, drawn to methods for determining a polymorphism of the amino acid sequence of the ABCG2 polypeptide.

Group III, claim(s) 9-15, drawn to polynucleotides.

Group IV, claim(s) 16 and 18, drawn to polypeptides and cells producing polypeptides.

Group V, claim(s) 17, drawn to antibodies.

Group VI, claim(s) 19, drawn to a method of measuring drug transport.

Group VII, claim(s) 9-18 and 22, drawn to kits comprising nucleic acids, polypeptides, and antibodies.

Group VII, claim(s) 23, drawn to a computer system.

2. The inventions listed as Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons:

A 371 case is considered to have unity of invention only when there is a technical relationship among those inventions involving one or more of the same or corresponding technical features. The expression "special technical feature" means those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. In the instant application, the linking technical feature of a method for determining a polymorphism of the nucleotide sequence of the ABCG2 gene does not constitute a contribution over the prior art. The claims of group I are so broad as to include any polymorphism of the ABCG2 gene. For example Imai et al (Molecular Cancer Therapeutics 2002 Vol 1, pages611-616) teach that they sequenced the entire coding region of BCRP (also known as ABCG2) cDNA generated by RT-PCR. In particular, Imai et al found two variant cDNAs (G34A substituting a Met for Val-12, and C421A substituting Lys for Gly –141). Thus, there is no special technical feature linking the recited groups, as would be necessary to fulfill the requirement for unity of invention.

Furthermore, the molecules of groups III, IV, and V do not share a corresponding structural property. The special technical feature of the nucleic acids of Group III is the identity of its monomers which are nucleotides and which determine its structure, properties and function. In contrast, the special technical feature of the proteins of Group IV are its amino acid monomers, which determine its structure, properties and function which are arranged in a specific 3-dimensional structure. The special technical feature of the antibodies of group V are also its amino acid monomers. However, in an antibody, the amino acids are arranged in a specific tertiary structure wherein four

subunits (2 light chains and 2 heavy chains) are joined via disulfide bonds. The antibodies of group V differ from the proteins of group IV with respect to their amino acid sequence, secondary and tertiary structure and their functional activities. While antibodies bind to specific target antigens and function in immunological reactions, such that they may neutralize an antigen, polynucleotides do not have these functional activities. Proteins may be used for therapeutic purposes or in ligand binding assays. Further, while nucleic acids may be used in hybridization assays, antibodies and proteins may not be utilized in hybridization assays. As the products differ from each other in structure, function, and effect, they do not belong to a recognized class of chemical compound, or have both a "common property or activity" and a common structure as would be required to show that the inventions are "of a similar nature".

Additionally, groups I, II, and VI are drawn to different methods such that each method requires different active process steps, require the use of different reagents and have different objectives, and do not share a special technical feature. The methods of group I require determining a polymorphism of the nucleotide sequence of the ABCG2 gene. These steps are not required to practice the methods of groups II and VI. The method of group II requires determining a polymorphism of the amino acid sequence of the ABCG2 polypeptide. These steps are not required to practice the methods of groups I or VI. The methods of group VI require measuring the amount of drug transport of a cell. These steps are not required to perform the methods of groups I or II. As such, each of the methods has a different objective and outcome and do not share a corresponding technical feature.

Sequence Election Requirement Applicable to All Groups

3. In addition, each invention detailed above reads on patentably distinct inventions drawn to multiple polymorphic sites. According to PCT Rule 13.2 and to the guidelines in Section (f)(i)(A) of Annex B of the PCT Administrative Instructions, all alternatives of a Markush Group must have a common property or activity. Although the chemical compounds share a common structure in that they are nucleic acids or are all proteins the compounds are not regarded as being of a similar nature because all of the alternatives do not share a common property or activity. Each of the nucleic acids consists of a unique nucleotide sequence, has a distinct melting temperature and a distinct specificity of hybridization. Each of the nucleic acids also encodes for a protein having a distinct amino acid sequence and a distinct biological activity. A search for one polymorphic site would not be co-extensive with a search for another polymorphic site. Further, a reference rendering one polymorphic site as anticipated or obvious over the prior art would not necessarily also render another polymorphic site as anticipated or obvious over the prior art. Similarly, a finding that one polymorphic site was novel and unobvious over the prior art would not necessarily extend to a finding that another polymorphic site was also novel and unobvious over the prior art. **In response to the restriction requirement, if Applicant elects an invention drawn to nucleic acids, the applicant must further elect a single polymorphic site selected from the group consisting of 34, 376, and 421 of SEQ ID NO: 1. Should Applicant elect an invention drawn to amino acids, the applicant must further elect a single**

polymorphic site selected from the group consisting of 12, 126, and 141 of SEQ ID NO: 2.

It is further noted that this is a restriction requirement and should **not** be construed as an election of species.

4. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the

rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda M. Shaw whose telephone number is (571) 272-8668. The examiner can normally be reached on Mon-Fri 7:30 TO 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RAM R. SHUKLA, PH.D.
SUPERVISORY PATENT EXAMINER